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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,743	02/14/2002	Royce Johnson	VAC.700	1606

7590 06/02/2004

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EXAMINER	
LEWIS, KIM M	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,743	JOHNSON ET AL.	
	Examiner	Art Unit	
	Kim M. Lewis	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/19/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 3/16/04 has been received and made of record. As requested, the abstract and claim 2 have been amended, and claim 2 has been canceled.

Claims 2-15 are pending in the instant application.

Information Disclosure Statement

2. The information disclosure statement filed 3/19/04 has been received and made of record in the application. Note the acknowledged form PTO-1449 enclosed herewith.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 2-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/05873 ("Lina et al.") in view of US Patent Application Publication No. 2003/0077311 A1 ("Vyakarnam et al.") and U.S. Patent No. 5,621,035 ("Lyles et al.)

As regards claims 2 and 7, Lina et al. disclose all features of the claimed invention including a porous foamed pad (36) shaped to conform to a wound (page 8, last paragraph), an air-tight seal (wound cover 43) adhered to the skin and/or pad (page 8, 2nd full paragraph), and a negative pressure source (vacuum pump 84) in fluid communication with the pad (page 9, 1st full paragraph).

As to the biocompatibility of the pad, since the pad can be placed on or within a wound cavity, the pad is inherently biocompatible. Also, on page 7, starting with the 3rd full paragraph, Lina et al. disclose the pad as being constructed from open cell polyurethane or polyether foam, both of which is biocompatible.

As to the removability of the air-tight seal (wound cover) from the pad, the examiner contends that the disclosed acrylic adhesive is capable of being removably attached to the pad in the same manner that it is removably attached to the skin.

In further regard to claims 2 and 7, Lina et al. fail to teach the biocompatible pad is comprised of an ultra-low density fused–fibrous ceramic.

Vyakarnam et al., however, disclose that it known to apply bioabsorbable polymer foams to various areas of the body in order to promote tissue regeneration. Further disclosed is the use of a ceramic particles or fibers in combination with the foam in order to reinforce the foam such that the foam is strengthened so as to be structurally compatible with cancellous bone (para. 0034).

Vyakarnam et al. fail to teach that the type of ceramic used is an ultra-low density fused-fibrous ceramic. However, Lyles et al. disclose the use of ultra-low density fused-fibrous ceramic. Lyles et al. teach that ultra-low density fused-fibrous ceramic have various desirable properties, such as for example, high tensile strength, dimensional stability, low thermal conductivity, etc. (col. 3,lines 30-63).

It would have been obvious to one having ordinary skill in the art to provide the foam pad of Lina et al. with a ceramic in order to strengthen the foam as taught by Vyakarnam et al.

It would have also been obvious to one having ordinary skill in the art to substitute the ceramic disclosed in Vyakarnam et al. for the ultra-low density fused-fibrous ceramic disclosed in Lyles et al., since Lyles et al. disclose that the ultra-low

density fused-fibrous ceramic have additional desired properties such as high tensile strength, dimensional stability, low thermal conductivity, etc.

Furthermore, the applicant fails to teach the criticality and/or unexpected results derived from providing **a pad that comprises from ultra-low density fused-fibrous ceramic.** As such, the examiner contends that other biocompatible pads would perform equally as well.

As regards claim 3, the foam disclosed in Lina et al. is an open-cell reticulated foam (page 7, last paragraph and page 8, 2nd full paragraph). Once modified and placed on/in a wound of a user, all of the foam does not touch the wound, see Fig. 10. Therefore, some of the ceramic particles will not touch the wound (*i.e.,* the foam is adhered to non-wound contacting surfaces of the ceramic).

As regards claim 4, the modified pad of Lina et al. as discussed in the rejection of claims 2 and 7 above, is removable from the ceramic in that it is bioabsorbable.

As regards claim 5, Lina et al. disclose that the pad is connected via hoses (37, 38) to a canister (19) and that the canister is connected to the pump. As can be read the last line on page 7, the hoses are preferably made from medical grade PVC tube. This tubing is inherently flexible.

As to claim 6, Lina et al. disclose that the canister is placed within recess (18) and can be removed therefrom (page 13, 2nd full paragraph).

As regards claim 8, note the rejection of claim 5 above.

As regards claim 9, note the rejection of claim 6 above.

1. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lina et al. in view of Vyakarnam et al.

As regards claim 10, Lina et al. substantially disclose all the features of the claimed invention including a pad comprised of branched polymers (polyurethane or polyether foam). Lina et al. fails to teach a pad comprised of biosorbable branched polymers.

Vyakarnam et al. disclose a foam composite comprised of biosorbable branched polymers because they are particularly well suited for tissue engineering (abstract and paragraph 50).

It would have been obvious to one having ordinary skill in the art to substitute the foam pad of Lina et al. with a foam pad comprised of a bioabsorbable foam because they are particularly well suited for tissue engineering, as taught by Vyakarnam et al.

As regards claim 11, note the rejection of claim 5 above.

As regards claim 12, note the rejection of claim 6 above.

2. Claim 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lina et al. in view of 4,614,794 (Easton et al.").

As regards claim 13, Lina et al. substantially disclose all features of the claim except that the pad comprises a cell-growth enhancing matrix. However, Easton et al. disclose a wound dressing (pad) comprising the biodegradable protein collagen, thereby teaching a cell-growth enhancing matrix for enhancing cellular growth.

It would have been obvious to one having ordinary skill in the art to add the wound dressing (pad) of Easton et al. to the pad of Lina et al. in order to enhance or improve cellular growth at the wound site. The applicant should note that Easton et al. teach that the wound dressing can be used in conjunction with conventional absorbents (col. 6, lines 41-47)

As regards claim 14, note the rejection of claim 5 above.

As regards claim 15, note the rejection of claim 6 above.

Response to Arguments

Applicants' primary argument is that neither claim 2 nor claim 7 combine a ceramic with the pad, as urged by the application of Vyakarnam et al. with Lina et al. And using a ceramic or pad, alone, would destroy the purpose of Vyakarnam et al, which emphasizes a transitional gradient throughout the pad. The examiner is unclear as to the point of applicants' argument since applicants' claim recites **"wherein said biocompatible pad is comprised of an ultra-low density fused-fibrous ceramic" (emphasis added by the examiner).**

Vyakarnam et al. disclose foam composites in the form of substrates (pads) that comprise ceramic particles or fibers (para. 0034). As stated in the rejection above, Vyakarnam et al. fail to teach the type of ceramic particles or fibers. However, Lyles et al. teach why one having ordinary skill in the art would select ultra-low density fused-fibrous ceramic as the ceramic material because of its desired properties of high tensile strength, dimensional stability, and low thermal conductivity.

Additionally argued is that the substitution of the pad of Vyakarnam et al. for the pad of Lina et al. would destroy the transitional gradient throughout the pad of Vyakarnam et al. and the ability of Lina et al. to create sufficient negative pressure. In each argued instance, the examiner disagrees. First, the applicant has not provided any evidence that the gradient forming purpose of Vyakarnam et al. in combination with Lina et al. would be destroyed. Also, the examiner is merely substituting the substrate (pad) of Vyakarnam et al. for the pad of Lina et al. And, in doing so, the integrity of the pad of Vyakarnam et al. is maintained. Next, since Vyakarnam et al. is silent as to the type of ceramic fibers or particles, which may be used in constructing the foam substrate, one having ordinary skill in the art would select ceramic fibers or particles that are best known for the strength. Lyles et al. provide one having ordinary skill in the art with a teaching of the use of ultra-low density fused-fibrous ceramic for their desired properties.

As to Applicants arugument that the combination of Vyakarnam et al. and Lina et al. in reference to claims 10-12, the applicant should note the both pad of Lina et al. and the substrate (pad) of Vyakarnam et al. are both open cell porous foam pads. Therefore, applicants' comments hat the Vyakarnam et al. teaching a transitional gradient throughout the pad and Lina et al. teaching an open-pore pad is not understood. Note the abstract of Vyakaranam et al.

Finally applicants' argues that Easton et al. teaches that the polysaccharides in the complex involve inflammatory reactions in the user of the complex, therefore, one of ordinary skill in the art would avoid any matrix complex of protein/polysaccharide due to

negative therapeutical implications of such a combination. In response, the examiner directs applicants back to col. 3, lines 8-13, which recites "These polysaccharides should be as pure as possible, in order to avoid inflammatory reactions...". It is important to note that "these polysaccharides" refer to the listed plant polysaccharides, of which collagen was not listed. Additionally, the applicants should note that the collagen disclosed is animal derived, not plant derived.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is

703.308.1191. The examiner can normally be reached on Mondays to Thursdays from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703.308.0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kim M. Lewis
Primary Examiner
Art Unit 3743

kml
June 1, 2004